

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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04 md. 1603 (SHS)

This document relates to:

06 Civ. 13095 (SHS)

07 Civ. 03972 (SHS)

07 Civ. 03973 (SHS)

07 Civ. 04810 (SHS)

In re:

OXYCONTIN ANTITRUST LITIGATION

**NONCONFIDENTIAL VERSION**

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**DECLARATION OF CASEY B. HOWARD IN SUPPORT OF MALLINCKRODT'S  
REPLY BRIEF ON THE UNENFORCEABILITY OF U.S.  
PATENT NOS. 5,549,912, 5,656,295, AND 5,508,042 DUE TO INEQUITABLE CONDUCT**

**CASEY B. HOWARD**, an attorney duly admitted to practice law in the State of New York, hereby affirms under penalty of perjury as follows:

1. I am an associate of the law firm of Locke Lord Bissell & Liddell LLP, counsel for Defendants. I submit this declaration in support of Mallinckrodt's Reply Brief on the Unenforceability of U.S. Patent Nos. 5,549,912, 5,656,295, and 5,508,042 Due to Inequitable Conduct.
2. Attached hereto as Exhibit 49 is a true and correct copy of a correspondence from Hugh L. Moore to John J. Normile on September 4, 2007.
3. Attached hereto as Exhibit 50 is a true and correct copy of a correspondence from John J. Normile to Hugh L. Moore on September 14, 2007.
4. Attached hereto as Exhibit 51 is a true and correct copy of excerpts from the deposition of Robert Kaiko, Ph.D. taken by Mallinckrodt on August 31, 2007.

Attached hereto as Exhibit 52 is a true and correct copy of Exhibit 9 to the deposition of Robert Kaiko, Ph.D. taken by Mallinckrodt on August 31, 2007

Redacted

6. Attached hereto as Exhibit 53 is a true and correct copy of Exhibit 10 to the deposition of Robert Kaiko, Ph.D. taken by Mallinckrodt on August 31, 2007

Redacted

7. Attached hereto as Exhibit 54 is a true and correct copy of Exhibit 11 to the deposition of Robert Kaiko, Ph.D. taken by Mallinckrodt on August 31, 2007

Redacted

8. Attached hereto as Exhibit 55 is a true and correct copy of Exhibit 12 to the deposition of Robert Kaiko, Ph.D. taken by Mallinckrodt on August 31, 2007

Redacted

9. Attached hereto as Exhibit 56 is a true and correct copy of excerpts from Purdue's OxyContin C.R. Tablets NDA #20-553 Final Study Report OC92-1001 ("the LoRusso study") titled "Double-Blind, Randomized q12h Multiple-Dose, Parallel-Group Comparison of the Pharmacokinetic and Pharmacodynamic Profiles of Controlled-Release Oxycodone (OxyContin<sup>TM</sup>) and MS Contin<sup>®</sup> Tablets in Patients with Chronic Cancer-Related Pain" dated February 20, 1997, admitted as PTX 717 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

10. Attached hereto as Exhibit 57 is a true and correct copy of excerpts from Purdue's OxyContin Study Report OC93-0303 ("the Kalso study") titled "Double-Blind Randomized,

Repeated Dose, Crossover Comparison of the Pharmacokinetic and Pharmacodynamic Profiles of Controlled-Release Oxycodone and Controlled-Release Morphine in Cancer Patients with Pain” dated October 17, 1996, admitted as PTX 475 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

11. Attached hereto as Exhibit 58 is a true and correct copy of a 1989 article titled “The United States Experience with Oral Controlled-Release Morphine (MS Contin Tablets): Parts I and II. Review of Nine Dose Titration Studies and Clinical Pharmacology of 15-mg, 30-mg, 60-mg, and 100-mg Tablet Strengths in Normal Subjects” by Robert Kaiko, Ph.D., *et al.*

12. Attached hereto as Exhibit 59 is a true and correct copy of a 1983 abstract titled “A Double Blind Cross-Over Study of Two Oral Formulations of Morphine” by J. Welsh, *et al.*, as cited in Exhibit 58, *supra*.

13. Attached hereto as Exhibit 60 is a true and correct copy of excerpts of the *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.* No. 00-civ-8029 Trial Record.

14. Attached hereto as Exhibit 61 is a true and correct copy of excerpts from the deposition of Clifford Davidson taken by Boehringer-Ingelheim, GMBH on July 11, 2001.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that this declaration was executed on October 19, 2007, in New York, New York.

A handwritten signature in black ink, appearing to read 'Casey B. Howard', written over a horizontal line.

Casey B. Howard